Safety Data Sheet
DOXAZOSIN TABLETS USP
Strength: 1 mg, 2 mg, 4 mg and 8 mg
Pack Size: 30's, 100's 1000's Tablets per bottle and Carton of 100 Tablets (10 x 10 unit Dose)
Revision No.: 00

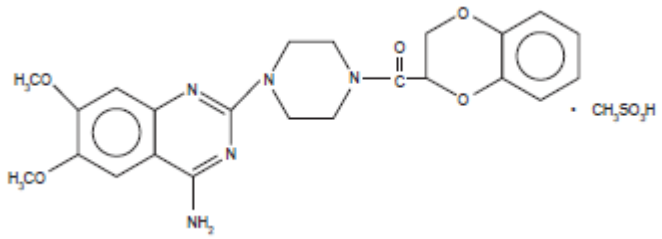
EMERGENCY OVERVIEW

Each Doxazosin Tablets USP intended for oral administration contains Doxazosin Tablets USP and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product Name:	Doxazosin Tablets USP
Formula:	$C_{23}H_{25}N_5O_5 \cdot CH_4O_3S$
Chemical Name:	1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-(1,4benzodioxan-2-ylcarbonyl)piperazine methanesulfonate.



Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd., Matoda, India**
Address:	Cadila Healthcare Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
Recommended use / Therapeutic Category	Doxazosin tablets are an alpha1 adrenergic antagonist indicated for: Signs and symptoms of Benign Prostatic Hyperplasia (BPH) Treatment of Hypertension
Restriction on Use / Contraindications:	Hypersensitivity to doxazosin, other quinazolines, or any other ingredient in doxazosin tablets.

Section 2. Hazard(s) Identification

Dose and Administration	For the treatment of BPH: Initiate therapy at 1 mg once daily. Dose maybe titrated at 1 to 2 week intervals, up to 8 mg once daily. For the treatment hypertension: Initiate therapy at 1 mg once daily. Dose may be titrated as needed, up to 16 mg once daily.

Adverse Effects	Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
Over Dose Effect	Experience with doxazosin overdosage is limited. Two adolescents, who each intentionally ingested 40 mg doxazosin with diclofenac or acetaminophen, were treated with gastric lavage with activated charcoal and made full recoveries. A two-year-old child who accidently ingested 4 mg doxazosin was treated with gastric lavage and remained normotensive during the five-hour emergency room observation period. A six-month-old child accidentally received a crushed 1 mg tablet of doxazosin and was reported to have been drowsy. A 32-year-old female with chronic renal failure, epilepsy, and depression intentionally ingested 60 mg doxazosin (blood level = 0.9 mcg/mL; normal values in hypertensives = 0.02 mcg/mL); death was attributed to a grand mal seizure resulting from hypotension. A 39-year-old female who ingested 70 mg doxazosin, alcohol, and Dalmane® (flurazepam) developed hypotension which responded to fluid therapy. The oral LD50 of doxazosin is greater than 1000 mg/kg in mice and rats. The most likely manifestation of overdosage would be hypotension, for which the usual treatment would be intravenous infusion of fluid. As doxazosin is highly protein bound, dialysis would not be indicated.
Contraindications	The use of doxazosin tablets is contraindicated in patients with a hypersensitivity to doxazosin, other quinazolines (e.g., prazosin, terazosin), or any of its components.
Pregnancy Comments	The limited available data with doxazosin in pregnant women are not sufficient to inform a drug-associated risk for major birth defects and miscarriage. However, untreated hypertension during pregnancy can result in increased maternal risks [see Clinical Considerations]. In animal reproduction studies, no adverse developmental effects were observed when doxazosin was orally administered to pregnant rabbits and rats during the period of organogenesis at doses of up to 41 and 20 mg/kg, respectively (exposures in rabbits and rats were 10 and 4 times, respectively, the human AUC exposures with a 12 mg/day therapeutic dose). A dosage regimen of 82 mg/kg/day in the rabbit was associated with reduced fetal survival The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S.

	general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.
Pregnancy Category	Not available

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Doxazosin mesylate	Not Found	77883-43-3
Inactive ingredients:		
Lactose Monohydrate	Not Found	9004-34-6
Microcrystalline Cellulose	Not Found	9004-34-6
Sodium Starch Glycolate Type A	Not Found	9063-38-1
Sodium lauryl Sulphate	Not Found	151-21-3
Magnesium stearate	Not Found	557-04-0
Ferric Oxide Red	Not Found	1309-37-1
Lake Blend LB-500006 purple	Not Found	NA

Section 4. First -aid measures

General	• **After inhalation:** Move to fresh air in case of accidental inhalation. assure fresh air breathing. • **After skin contact:** Rinse skin with water/shower • **After eye contact:** Rinse with water while holding the eyes wide open. Contact lenses should be removed. • **After swallowing:** Rinse mouth out with water • **Information for doctor:** • **Most important symptoms and effects, both acute and delayed-** No further relevant information available. • **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.
Overdose Treatment	Limited data are available related to overdosage in humans. If symptomatic hypotension occurs, initiate supportive treatment.

Section 5. Fire -fighting measures	
	Extinguishing media · **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. · **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not · **Protective equipment:** Hand protection : Gloves Skin and body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted
Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.
Environmental precautions:	No additional information available
Methods and material for containment and cleaning up:	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.
Section 7. Handling and Storage	
Storage:	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].Dispense in tight container. **Precautions for safe handling**: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.

Section 8. Exposure controls / personal protection

Respiratory Protection	Quarter mask (DIN EN 140)
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance	Description of Doxazosin Tablets USP , 1 mg is white to off-white, round, biconvex scored uncoated tablets debossed '783' on one side and Score line on other side Description of Doxazosin Tablets USP , 2 mg is Light Pink to pink , mottled ,round, biconvex scored uncoated tablets debossed '784' on one side and score line on another side Description of Doxazosin Tablets USP , 4 mg is Light Pink to pink , mottled ,capsule shaped , biconvex scored uncoated tablets debossed '785' on one side and score line on another side Description of Doxazosin Tablets USP , 8 mg is Light Purple to Purple , mottled ,round, biconvex scored uncoated tablets debossed '786' on one side and score line on other side		
Solubility	Not available	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Hazardous reactions	No dangerous reaction known under conditions of normal use.

Decomposition products	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent
Section 11. Toxicological information	
General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Other	Not Available
Symptoms related to the physical, chemical and Toxicological characteristics	Not available
Information on toxicological effects	
Acute toxicity	Not available
Further information	Not available
Section 12. Ecological information	
	Poorly soluble in water. No data available on ecotoxicity.
Section 13. Disposal Consideration	
	Dispose the waste in accordance with all applicable Federal, State and local laws.
Section 14. Transport Information	
	The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN
Section 15. Regulatory Information	
	Generic Medicine. Under Approval by USFDA & the ANDA Number is 208719
Section 16. Other information	
	None

Date of issue: 21/08/17 **Supersedes edition:** New Edition

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.